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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
- 09/915,853	07/26/2001	Takafumi Ueno	12013/58002	7372

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/09/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/915,853

Applicant(s)

UENO ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,5,7,9-11,13-15,18,20,22,24,28,29,31,33,38,40,41 and 43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 2,5,7,9-11,13-15,18,20,22,24,28,29,31,33,38,40,41 and 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/11/2003 has been entered.
2. Claims 8,21,30,39,42, and 70-73 are canceled without prejudice or disclaimer. Claims 2,5,7,9-11,13-15,18,20,22,24,28-29,31,33,38,40-41,and 43 are therefore pending and examined on the merits.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 2,5,7,9-11,13-15,18,20,22,24,28-29,31,33,38,40-41,and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi *et al* (cited in prior office actions).

Claims are drawn to a method of forming new blood vessels in cardiac muscle tissue in a human comprising the isolating of autologous bone marrow mononuclear cells (BM-MNCs) from a human, and transplanting into cardiac tissue an effective amount of the BM-MNCs (claim 9); wherein the cardiac tissue is ischemic (claim 2), or damaged cardiac tissue (claim 5), wherein the damage is an artificially created site (claim 7); wherein the blood vessels comprise capillaries (claim 10) or collateral vessels (claim 11). The claims are further drawn to a method of inceasing blood flow to cardiac muscle tissue comprising the isolating of autologous BM-MNCs from a human, and transplanting into cardiac tissue an effective amount of the BM-MNCs (claim 22); wherein the cardiac tissue is ischemic (claim 15), or damaged cardiac tissue (claim 18), wherein the damage is an artificially created site (claim 20); wherein the blood vessels comprise capillaries (claim 13) or collateral vessels (claim 14). The claims are also drawn to a method of treating a diseased cardiac muscle tissue comprising the isolating of autologous BM-MNCs from a human, and transplanting into cardiac tissue an effective amount of the BM-MNCs (claim 31); wherein the cardiac tissue is ischemic (claim 24); wherein the blood vessels comprise capillaries (claim 28) or collateral

vessels (claim 29). The claims are also drawn to a method of increasing angiogenesis in diseased cardiac tissue comprising the isolating of autologous BM-MNCs from a human, and transplanting into cardiac tissue an effective amount of the BM-MNCs (claim 38); wherein the cardiac tissue is ischemic (claim 33). And lastly, the claims are drawn to a method of treating heart failure comprising the isolating of autologous BM-MNCs from a human, and transplanting into cardiac tissue an effective amount of the BM-MNCs (claim 43); wherein the blood vessels are capillaries (claim 40) or collateral vessels (claim 41).

Kobayashi *et al* teach a method of administering to a mammal autologous bone marrow (BM) cells for the enhancement of angiogenesis in an in vivo heart model. It is taught by Kobayashi *et al* that the in vivo administration of BM to artificially created ischemic regions of the heart caused elevated angiogenesis in these ischemic regions or myocardial infarct (MI) regions. Kobayashi *et al* further indicated that BM cells contain many different types of immature cells which could differentiate into hematopoietic cells and endothelial progenitor cells (EPC-- cells involved in the formation of blood vessels). Although not characterized as having administered mononuclear cells (MNC), the BM cells administered by Kobayashi *et al* would also contain the MNCs.

Therefore, it would have been *prima facie* obvious at the time the invention was made to one of ordinary skill in the art to treat ischemic tissue by administering BM-MNCs from a human to generate the formation of capillaries or collateral vessels through angiogenesis. One of skill would have been motivated to do so because the

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administration of BM cells by Kobayashi *et al* resulted in the revascularization of the ischemic region through angiogenesis in a rat ischemic heart model. The BM cells administered by Kobayashi *et al* achieved the same result of administering the BM-MNCs as that instantly claimed, and because the BM cells also contain BM-MNCs, one of skill would have reasonable expectation that BM when administered would result in the same collateral and capillary formation. It is noted that the claims recite isolated BM-MNCs, however, there is no specific recitation or limitation which refers the purity of the isolation. One of skill would have found reasonable motivation to do so in humans because the administration of BM to ischemic regions in the in vivo model taught by Kobayashi *et al* was successful in revascularizing the damaged heart tissue, and one of skill would have reasonable expectation that such a model is predictive of human success.

All other rejections of record are withdrawn in view of the amendments and arguments thereto as set forth in paper no. 17

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
for:

Christopher Yaen
Art Unit 1642
August 27, 2003